Section 5.0

510(k) Summary

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K110286

510(k) Information

APR 2 8 2011

New Device	
Submission Type:	Traditional
Reason for Submission:	New Device
Device/Trade Name:	Type 1053 FreeFit
Common Name:	Real Ear Measurement System (i.e., Audio Fitting System)
Classification Name:	Calibrator, Hearing Aid/Earphone And Analysis Systems
FDA CFR Section:	FDA 21CFR 874.3310
Classification Panel:	Ear, Nose, and Throat
Device Class:	Class II
Device Product Code:	ETW

Predicate Device	
Product Name:	SpeechLink 100 Type 1053
510(k) Number:	K061104
Classification Name:	Calibrator, Hearing Aid/Earphone And Analysis Systems
FDA CFR Section:	FDA 21CFR 874.3310
Device Product Code:	ETW
Manufacturer Name:	GN Otometrics A/S

Submitter/Owner:	GN Otometrics A/S Dybendalsvaenget 2 DK-2630 Taastrup Denmark
Establishment Registration No.:	9612197
Contact:	Tom Riniker RA/QA triniker.ext@gnotometrics.dk (612) 865-7862
Date of Preparation:	October 12, 2010

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Description of the Device

The GN Otometrics Type 1053 FreeFit is a PC-based system that contains hardware and software for one or more applications. The applications are controlled from self-contained software modules installed on a common software platform. The following applications are available: Real ear measurement system (i.e., audio fitting system) and Simulator system.

As a real ear measurement system, the Type 1053 FreeFit plays calibrated sound files and measures the sound pressure level in the ear canal. The difference between the measured sound level outside the ear and in the ear canal gives the gain from the hearing aid. This allows for adjusting hearing aids and demonstrating hearing aid features like noise suppression. The Type 1053 FreeFit system also shows target curves that the hearing aid dispenser can use as guidelines for adjusting the hearing aid.

The real ear measurement system consists of a neckset, a charger unit with mains adapter, two probes connected to the neckset, software for installation on a PC (i.e., OTOsuite Probe Microphone Measurements (PMM)) and hardware for connection to a PC. The neckset is connected to the PC via a Bluetooth radio link (i.e. no physical connection to the PC).

The FreeFit Neckset is the actual measuring device. It contains 2 probes (one for each ear) each with 2 microphones used for measuring the sound level outside and inside the ear. Digital signal processing in form of Fast Fourier Transformations takes place inside the device and the obtained frequency spectra are transmitted to the OTOsuite via Bluetooth. The microphones measuring outside the ear are used for calibrating the sound level. Measurements inside the ear canal (near the eardrum) are conducted with a biocompatible silicone tube guiding the sound waves to the microphone. And the probes contain an o-ring also in biocompatible material for fastening at the ear (pinna).

The FreeFit Charger is used to charge the FreeFit neckset via an inductive coil system. The charger includes a power adaptor connected to mains and providing DC input to the charger stand.

OTOsuite PMM is a software platform required for measuring with the Type 1053 FreeFit, displaying the results and controlling the played sound files and levels. OTOsuite runs on most windows based PCs.

The Type 1053 FreeFit also has the capability to act as a hearing loss simulator and a hearing instrument simulator. These applications are commonly used to demonstrate

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the level of hearing loss suffered by a patient and the degree to which that loss can be overcome by use of a hearing instrument.

The simulator consists of software for installation on a PC (i.e., OTOsuite Counseling and Simulation (C&S)) and hardware for connection to a PC (i.e., headphones).

OTOsuite C&S is a software application that is required for simulating hearing loss and hearing instruments as part of the counseling process.

Indications For Use/Intended Use

Type 1053 FreeFit is intended for audiologists, hearing instrument dispensers, ENTs, speech therapists and other health care professionals. The intended use is that the user is able to visualize the amplified signal recorded in the ear(s) of persons with a hearing loss together with reference information such as target curves in order for the user to have an objective basis for adjusting the Hearing Instrument settings.

Note also that the Type 1053 FreeFit is designed for use in combination with NOAHLink -HIMSA's wireless hearing instrument programming device.

Comparison to Predicate Device

Fitting systems like the Type 1053 FreeFit have been produced for decades. The system most similar to the Type 1053 FreeFit in terms of mechanical design and features is the SpeechLink 100 Type 1053 (SpeechLink 100) from GN Otometrics, upon which the Type 1053 FreeFit is based. Therefore, the design of the Type 1053 FreeFit represents an incremental improvement to an existing design.

In terms of mechanical parts and the probes, only cosmetic differences have been implemented in the new Type 1053 FreeFit. The reason for these changes is merely to make it easier to distinguish between the two products for marketing purposes. All other aspects of the mechanical and electrical design are the same.

From a measurement perspective, the two systems utilize very similar signal processing within the device, and both send resulting spectra values to the PC via Bluetooth.

The primary difference between the two devices is associated with software. The OTOsuite software used with the Type 1053 FreeFit contains additional features that did not exist in the SpeechLink 100. The development of an improved calibration scheme has led to significantly greater measurement accuracy. As a result, gain

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curves can now be accurately calculated by subtracting the frequency spectrum for the microphone outside the ear from the spectrum measured near the ear drum. Furthermore, this improved accuracy allows for effective comparison with target curves.

Substantial Equivalence Performance Data

Substantial equivalence to the SpeechLink 100 is based on a side-by-side design comparison, as well as non-clinical performance testing of the device against the applicable parameters specified in the ANSI S3.46 1997 Standard (i.e., Methods of Measurement of Real-Ear Performance Characteristics of Hearing Aids). This is further supported by the similar test results obtained from both devices as a result of testing to the other six standards listed below.

Conclusions About Safety and Effectiveness

Evaluating the results of testing to the following key standards has allowed us to make conclusions about the safety and effectiveness of the Type 1053 FreeFit.

1. IEC 60601-1	Medical Electrical Equipment. Part 1: General requirements for safety
2. EN/IEC 60601-1-2*	Medical Electrical Equipment. Part 1: General requirements for safety. 1. Collateral standard: Electromagnetic compatibility – Requirements and tests
3. IEC 60601-1-4	Medical Electrical Equipment. Part 1: General requirements for safety. 4. Collateral standard: Programmable electrical medical systems (Design process)
4. EN/IEC 61669*	Electroacoustics – Equipment for the measurement of real-ear acoustical characteristics of hearing aids
5. ANSI S3.46	Methods for Measurement of Real-Ear Performance Characteristics of Hearing Aids
6. ISO 10993-5	Biological Evaluation of Medical Devices: Tests for Cytotoxicity
7. ISO 10993-10	Biological Evaluation of Medical Devices: Tests for irritation and delayed-type hypersensitivity

**Since the EN standard is based directly on the IEC version recognized by the FDA, there are no material differences between the two. Therefore, we propose that compliance with the EN version of the standard provides an extremely high level of confidence that the device also complies with the IEC version of the standard.*

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The equivalent results from both the Type 1053 FreeFit and the SpeechLink 100 obtained when each device was tested to determine compliance with the aforementioned standards clearly demonstrates the substantial equivalence between these two devices.

Since the Type 1053 FreeFit device shares the same materials, hardware, and electronics as the SpeechLink 100 Type 1053 (a 510(k) cleared device – K061104) it stands to reason that the results obtained from IEC 60601-1, EN/IEC 60601-1-2, ISO 10993-5, and ISO 10993-10 are the same.

Since the Type 1053 FreeFit device and the SpeechLink 100 Type 1053 were both developed by GN Otometrics A/S using the same design and development process, it also is understandable that the results of an IEC 60601-1-4 evaluation would also be the same.

Lastly, although the minor differences that do exist between the two devices are in the area of software, these changes are due to improvements in the Type 1053 FreeFit software that serve to make the device more effective than its predecessor. This is supported by the positive results of testing to EN/IEC 61669 and ANSI S3.46.

Based on the results of testing to the applicable requirements of the aforementioned standards and achieving compliance to them, we hereby conclude that the Type 1053 FreeFit device is both safe and effective.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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c/o Ms. Paula Wilkerson
Intertek Testing Services
2307 East Aurora Road
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Twinsburg, OH 44087

APR 2 8 2011

Re: K110286
Trade/Device Name: GN Otometrics Type 1053 FreeFit
Regulation Number: 21 CFR 874.3310
Regulation Name: Hearing Aid Calibrator and analysis system
Regulatory Class: Class II
Product Code: ETW
Dated: January 28, 2011
Received: January 31, 2011

Dear Ms. Wilkerson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

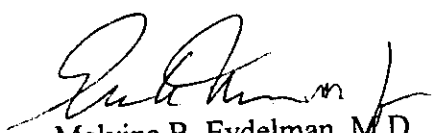
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4.0
Indications for Use

510(k) Number (if known): _____

Device Name: Type 1053 FreeFit

Indications for Use:

Type 1053 FreeFit

Type 1053 FreeFit is intended for audiologists, hearing instrument dispensers, ENTs, speech therapists and other health care professionals. The intended use is that the user is able to visualize the amplified signal recorded in the ear(s) of persons with a hearing loss together with reference information such as target curves in order for the user to have an objective basis for adjusting the Hearing Instrument settings.

Note also that the Type 1053 FreeFit is designed for use in combination with NOAHLink - HIMSA's wireless hearing instrument programming device.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K110286